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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M

A2

(11) International Publication Number: WO 99/53974

(43) International Publication Date: 28 October 1999 (28.10.99)

(21) International Application Number: PCT/US99/08870

(22) International Filing Date: 22 April 1999 (22.04.99)

(30) Priority Data:
09/064,352 22 April 1998 (22.04.98) US

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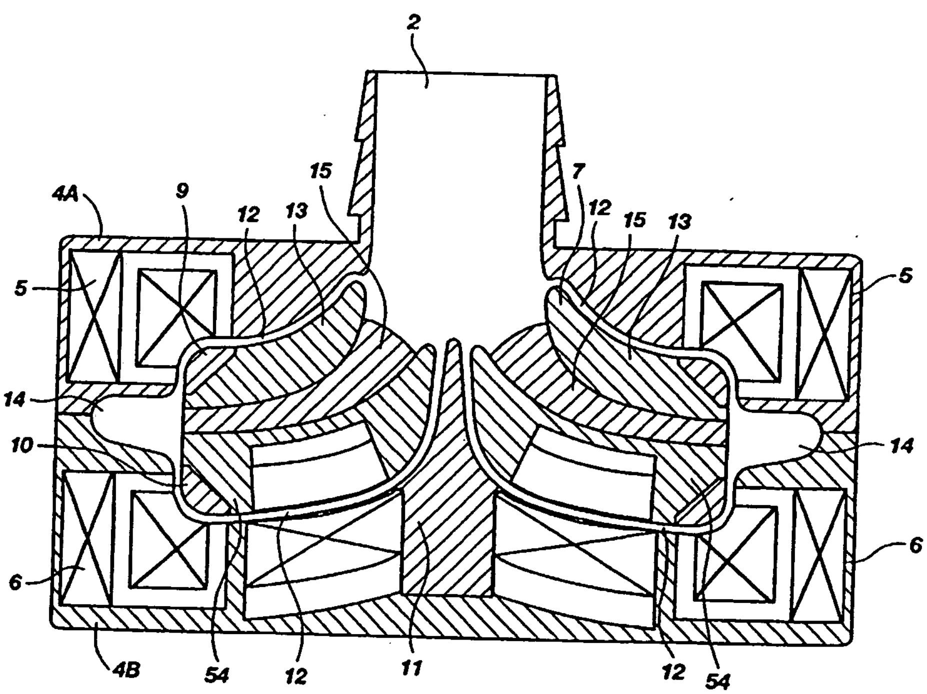
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: IMPLANTABLE CENTRIFUGAL BLOOD PUMP WITH HYBRID MAGNETIC BEARINGS

(57) Abstract



A pump for pumping sensitive fluids, such as blood, having no mechanical contact between the impeller and any other structure. The pump comprises a pump housing, an impeller disposed within the pump housing, a magnetic bearing system for supporting and stabilizing the impeller in five degrees of freedom, and a conformally shaped magnetically linked motor for rotating the impeller. The magnetic bearing system and motor advantageously comprise electromagnets and permanent magnets for stability and control of the impeller, and to reduce size, weight, and pump power consumption. Permanent and electromagnets are disposed on the pump housing and permanent magnets are disposed on the impeller such that by controlling electric current through the electromagnets on the housing, the magnetically suspended impeller functions as the rotor, and the housing as the stator of a D.C. motor. The system advantageously allows for sensing of relative impeller position and dynamic properties without the need for additional sensors. The fluid inlet, pump impeller, housing, and other components are configured such that flow patterns are as smooth and laminar as possible to reduce damage to the fluid, and such that eddies, flow separation, and re-circulation are reduced. In various embodiments, the pump is suitable for short or long-term implantation as a ventricular assist device or as a complete replacement heart in a human patient.

IMPLANTABLE CENTRIFUGAL BLOOD PUMP WITH HYBRID MAGNETIC BEARINGS

RELATED APPLICATION

The present application claims priority from United States nonprovisional patent application Serial No. 09/064,352, filed 04/22/98.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to pumps for pumping fluids such as blood that are sensitive to mechanical working or shear stress. More particularly, the present invention relates to a pump apparatus having an impeller that is magnetically suspended and rotated by electric and permanent magnets with no mechanical contact between the impeller and any other part of the pump.

State of the Art

There are many types of fluid pumps suitable for use in a wide range of applications, all performing the same basic function of moving fluid from one point to another, or moving a fluid from one energy level to another. However, pumps for pumping sensitive fluids, such as blood, introduce special design requirements. Additionally, pumps for implantation in a human patient for long or short-term use as ventricular assist devices (VAD's) or complete heart replacement, add additional size, weight, durability, and other requirements.

The design problems associated with sensitive fluids, including blood, generally relate to problems caused by contact of the fluid with mechanical parts and other substances present in the pump. Problem contact areas for sensitive fluids may include 1) contact with materials and structures in rotating fluid seals, 2)

magnetically suspended or levitated within the pump housing. and is magnetically. not mechanically. coupled to the pump housing. The pump employs permanent magnets rotating on a motor external to the pumping chamber. with the external permanent magnets magnetically coupled to opposing permanent magnets on the impeller. Magnetically suspended pumps are well adapted to pumping sensitive fluids because they eliminate the mechanical bearing structure or rotating seals which can damage or be damaged by the fluid.

However. such pumps that are currently known in the art present several drawbacks. First. an external motor with its own means of bearing support (ball bearings) is still required to rotate the impeller. It is the external bearing support that maintains the position of the rotor in such a pump. Though the motor is sealed from contact with blood and other bodily fluids. and is magnetically coupled to the suspended impeller. it still employs bearings which produce heat and pose the potential of failure. Naturally. such pumps tend to be bulky in part because of the size of the electric motor. These pumps are frequently unsuitable for implantation in a human patient because of size. weight. power consumption. and durability problems.

Other methods of magnetically supporting a rotating pump impeller have been developed. Olsen. et. al. (US Patent No. 4.688.998) teaches a fully suspended pump rotor employing permanent magnet rings on the rotor magnetized along the axis of rotation. and actively controlled electromagnets on the stator that create a magnetic field to stabilize the position of the rotor. This approach also leaves certain problems unsolved. While the manufacture of permanent magnets has advanced substantially. there are still significant process variations. These variations include repeatability from one magnet to the next. and homogeneity of the material within one magnet. The position and stability of the rotor

that are inherently available without adding additional sensors, such as magnetic bearing current and/or motor current sensors, that can be used as an indicator of required flow and pressure when the pump is implanted in the human body, or can be used to keep the impeller controlled by the magnetic bearing.

It is still another object of the present invention to provide a pump apparatus with a long product life which requires minimal maintenance.

It is still another object of the present invention to provide a pump apparatus that can provide flow in either a constant manner or a flow that pulses on a periodic basis.

It is yet another object of the present invention to provide a pump apparatus which is configured to cause an acute change in direction of the fluid in one or more of the conduits while still handling the sensitive fluid in a gentle manner.

It is another object of the present invention to provide a blood pump in which all blood-contacting surfaces are coated with a biocompatible ceramic coating.

The above and other objects of the invention are realized in specific illustrated embodiments of an implantable centrifugal blood pump with hybrid magnetic bearings. The pump comprises a generally cylindrical pump housing, a generally cylindrical impeller disposed within the pump housing, a magnetic bearing system for supporting and stabilizing the impeller in five degrees of freedom, and a conformally shaped motor for rotating the impeller in the remaining degree of freedom, with no mechanical contact between the impeller and any other structure. The pump thus reduces damage to the fluid from the pump and damage to the pump from the fluid. The pump impeller, housing, and other components are also configured such that flow patterns are as smooth and laminar as possible, and eddies, flow separation, and re-circulation are reduced.

FIG. 5B is a cross sectional view of the pump motor assembly;

FIG. 5C provides a view of the back of the pump motor assembly;

FIG. 6A is a view of the front of the motor rotor assembly;

FIG. 6B is a cross sectional view of the motor rotor assembly;

FIG. 6C depicts the polarity of the permanent magnets on the motor rotor in one embodiment;

FIG. 7A is a detailed front view of the motor coils on the stator;

FIG. 7B is a cross sectional view of the stator;

FIG. 7C is a view of the back of the stator;

FIG. 7D depicts the polarity of the three-phase windings on the stator in one embodiment of the invention;

FIG. 8 is a pictorial view of a hybrid EM/PM magnetic bearing ring;

FIG. 9 is a cutaway view of part of a hybrid EM/PM magnetic bearing ring showing the flux paths for one permanent magnet;

FIG. 10 depicts a preferred embodiment of the magnetic suspension actuator similar to Figure 9, but including the coils.

FIG. 11 is a cutaway view of part of a hybrid EM/PM magnetic bearing ring showing the flux paths for two electromagnets;

FIG. 12 shows an exploded pictorial view of the four bearing sets of poles, air gaps, and targets;

FIG. 13 shows a block diagram of an electronic controller for providing control of the magnetic bearing actuator;

FIG. 14 shows a representative applied voltage waveform and resulting representative current waveforms for two different positions of the rotating impeller;

FIG. 15 shows one implementation of the self-sensing electronic circuit; and

bearing actuator 5, and an outlet side magnetic bearing actuator 6. The impeller assembly 7 is disposed between the magnetic bearing actuators 5 and 6, and comprises the rotating part of the pump. The impeller 7 is designed to function as the rotor of a motor, and includes soft iron magnetic material structures 9 and 10 that act as targets on the rotor for the magnetic bearing actuators 5 and 6. These and other features of the impeller will be more apparent from the discussion of FIG. 3. The eye of the impeller 8 provides an opening for the inlet of flow into the pump vanes in the preferred embodiment. Advantageously, the motor stator 11 is incorporated in the outlet side or lower half 4B of the pump housing 4.

Figure 3 shows a two-dimensional cross sectional view of the inner workings of the preferred embodiment of the invention. In this view the combination of electromagnets (EM) and permanent magnets (PM) becomes visible. Advantageously, the impeller assembly 7 is the only moving part in the system, and forms a curved, conical ring disposed adjacent to the motor stator 11, and between the upper and lower bearing actuators 5 and 6. The impeller assembly 7 comprises a shroud 13 disposed above a plurality of vanes 15, and a hub 54 which supports the vanes and the elements of the motor rotor. The housing 4 is formed to provide curved fluid gaps 12 around the rotating impeller 7. The gaps 12 are configured to work in conjunction with the impeller 7 to accommodate flow without damaging blood or other sensitive fluids. This is accomplished by making the flow passage clearances 12 short in length, yet with large bending radii to allow gentle backflow around the shroud 13 and hub 54.

The vanes 15 of the impeller 7 drive the fluid from adjacent the inlet 2 into the pump volute 14, which is formed around the perimeter of the inner space of the housing 4. The volute 14 is formed in a logarithmic spiral shape, more evident in FIG. 2, which

designed to provide a smooth transition from the inlet blade angle to the discharge blade angle. It will be apparent from this figure that the inlet blade angle θ varies continuously from hub to shroud, with a greater angle θ near the inlet 2, and an angle approaching zero near the outlet (measured relative to a line perpendicular to the plane of the impeller), to reduce the incidence of flow angles over the entire blade length.

The pump intentionally allows relatively high leakage flows in the gaps 12 at the shroud side of the impeller, and along the hub side of the impeller. Relatively large fluid gaps are desirable on both the inlet side and discharge side of the impeller to allow for recirculating flows in the gaps at low shear stress levels. As will be appreciated, the acceptable level of shear is a function of expected cell transit time through the gap. However, for both magnetic bearing and motor design considerations, it is desirable to minimize the size of the flux gap. To balance these opposing factors, the inventors have experimented with gaps of various sizes, and have determined that a gap of 0.015 inches (15 mils) is presently preferred. However, it will be apparent that other gap sizes, such as 10, 20, and 30 mils may also be found suitable, and the inventors anticipate further study of these options using flow visualization.

Figure 5B shows a two-dimensional cross sectional view of the motor assembly, and figures 5A and 5C are front and back views of the same. The motor stator assembly 11 comprises motor coils 16 having a nonmagnetic core, backed by a backing material 17, preferably a soft iron magnetic material which may be laminated or not. Alternatively the backing material 17 may be formed of a non magnetic material depending on the level of constant force desired between the rotor and stator. In the preferred embodiment, the backing material 17 is laminated soft iron material. The

it only generates rotational forces or generates primarily rotational forces. This is a very important advantage in a system that uses magnetic bearings, since the size and power level of the magnetic bearings depends on the magnitude of the forces other than rotational force generated by the motor. Prior art integrated pump designs for sensitive fluids do not use this approach. Additionally, this motor is a slotless motor because the coils do not comprise a magnetic core, and the magnetic material 17 is thus separated from the permanent magnets in the rotor by the dimension of the coils 16.

The support of the rotating impeller requires control of five degrees of freedom: 3 translations (x,y,z) and 2 angular displacements (q_x and q_y). There are several types of forces which act upon the impeller: fluid forces, gravitational forces, and dynamic forces. The fluid forces are due to fluid pressures acting on the impeller and the changes in momentum as the flow direction is changed. The gravitational force (vertically downward) is due to the difference between the weight of the impeller and the buoyant force, in blood, acting on the impeller in different orientations, depending on the orientation of the body relative to the vertical. Dynamic forces act upon the impeller due to bodily accelerations during such activities as sudden motions, impact after a fall, etc.

The hybrid integrated EM/PM bearing of the present invention uses flux from both an electromagnetic flux source and a permanent magnetic flux source in the same integrated multiple pole configurations to control the five degrees of freedom. The permanent magnet (PM) circuit is integrated into a ring configuration with the electromagnet (EM) soft iron magnetic circuits, the EM coils, the magnet target, and a saturation link.

Figure 8 shows a pictorial view of the preferred embodiment of a bearing actuator 5 (or 6) with permanent magnets 21 and soft

provided by a bias current through the EM bearing coils, with a resulting much higher steady state power loss.

Blood and other fluids that are sensitive to heating are easily accommodated by this invention, because the innovative magnetic bearing design reduces power dissipated in the magnetic bearings as compared to prior art systems. This is accomplished, in part, by the use of permanent magnets. While permanent magnets have been employed in some prior art blood pumps, the embodiments in this invention present advantages in terms of 1) size of the magnetic bearing system, 2) bearing stiffness achieved in this configuration of the permanent magnets, and 3) power dissipated in the magnetic bearings.

Figure 10 shows an exploded view of a preferred embodiment of the magnetic suspension actuator 5 similar to Figure 9, but including coils 26, and shown in an orientation inverted from figure 8. The PM flux is directly integrated into a multiple pole ring configuration with the EM flux. Wire coils 26 suitable for providing a MMF in the EM section of the ring configuration are included in the construction. The radial and axial gap fluxes are varied with the EM flux, where the EM flux is adjusted by the coil currents to control the impeller position. The bearings have two EM flux paths: one that has a path including a radially oriented flux gap, and another containing an axially oriented flux gap. Both of these flux paths have a combination of EM and PM flux existing in them.

Figure 11 shows the EM flux paths. When it is desired to increase the magnetic flux in the air gap to increase the force acting on the impeller target, the corresponding coil current is increased the necessary amount. Alternatively when it is desired to decrease the magnetic flux in the air gap to decrease the force acting on the impeller target, the corresponding coil current is

configured for use with the present invention operates as follows. To move the rotor in the positive Y direction (radial), it is necessary to produce a radial force, but not simultaneously produce an axial force, so as to keep the impeller/rotor in the centered position. The EM coils in the top of the rotor are activated so that the magnetic flux in the inlet side axial flux gap 29 and discharge side axial flux gaps 30 is increased equally and activate the other top EM coils so that the flux in the inlet side radial flux gap 27 and discharge side radial flux gap 28 are decreased equally. The coils in the bottom of the rotor are activated so that the flux in the inlet side radial flux gap 31 and discharge side radial flux gap 32 are increased equally and activate the other EM coils so that the flux in the inlet side axial flux gap 34 and discharge side axial flux gaps 33 are decreased equally. This combination produces a net radial force downward, opposite to the upward motion of the rotor, and no net axial force. Reversing this combination creates a net upward force if the impeller moves downward. A similar combination of EM coil currents produces a net axial force or moments about the x or y axes without any radial force. If the inlet and discharge side rings are not identical, a relatively simple control algorithm, based on the differing pole face areas and flux levels, is used to decouple the forces and moments generated to center the impeller/rotor.

The magnetic bearing actuator is controlled by an electronic controller 36, which is included in the block diagram of Figure 13. Conventional magnetic bearings require physical sensors to provide feedback control signal to a controller. However, in the present invention, there are no physical sensors employed. Instead, the controller 36 constantly monitors and evaluates the impeller position by means of a passive self-sensing system. The position of the rotor is measured using a self-sensing algorithm, which

The magnetic bearing actuator is controlled by adjusting the EM coil currents and creating magnetic forces needed to center the impeller. The control algorithm is a feedback controller employing a signal correlated with the translational displacements of the impeller in three directions and two angular displacements in two axes perpendicular to the motor spin axis, represented as $x(t)$. The controller operates on a mathematical model of the magnetic bearing geometry and magnetic properties including both the EM and PM flux paths, the electrical properties of the bearing EM coils, the properties of the power amplifiers, properties of the preamplifiers, and the translational and angular displacement sensing circuits.

The controller algorithm may consist of a proportional-integer-derivative controller, where the control signal $G(t)$ has three components: 1) proportional to the translational or angular displacements with constant K_p, 2) proportional to the time integral of the translational or angular displacements with constant K_i, and 3) proportional to the translational or angular velocity of the form with constant K_d.

$$G(t) = K_p x(t) + K_i \int x(t)dt + K_d \frac{dx(t)}{dt}$$

Alternatively, the controller may take the form of mu synthesis, or similar controller, for a controller where feedback is used and the controller is able to take into account uncertainties in the mathematical model of the system. Another possible controller algorithm is the use of a sliding mode (variable structure control) which employs a reaching condition to place the impeller translational displacements and angular displacements on a hyperplane (sliding surface in phase space), known to practitioners of the art, and create a condition where the impeller states are moved along the hyperplane. The controller currents are switched on when the impeller

There are several advantages to this approach. First, the physical size of the pump can be reduced because there is no space required for sensors. Second, physical sensors are potential points of failure and the passive electronic sensing system should be more reliable. Third, the number of wires coming off of the heart pump is significantly less. As an illustration of the self-sensing concept, Figure 14 shows an applied voltage waveform 38 and the resulting current waveforms for two different positions of the rotating impeller. The current for position 1 is denoted at 39, and the current for position 2 is denoted at 40. The overall envelope of the position 1 current is denoted at 41, and the envelope for the position 2 current is denoted at 42. Average currents for position 1 and position 2 are denoted at 43 and 44 respectively.

Figure 15 shows the implementation of the self-sensing electronic circuit 37. Filters 45 operate on the current signal obtained from the switching amplifier 35, resulting in the envelope and average value waveforms. The envelope, average value, and applied voltage are fed into the digital sampling system 46 where the variation in current waveform envelope relative to the average current and the applied voltage is used to determine the electrical time constant of the resistance-inductance circuit in the actuator. From this information, the inductance, and hence the rotor position can be derived. An alternative approach is to sample the current waveform directly. The approach of this invention thus provides the significant advantage of lowering the required sampling rate of the digital sampling system significantly, while still obtaining all of the necessary information from the waveforms.

This sensing approach eliminates the separate position sensors used in prior art systems with the following advantages: 1) smaller system size 2) improved reliability due to decrease number of

to fluid shear, 2) thrombogenesis due to flow stagnation and/or fluid shear, and 3) material interactions with blood that result in thrombogenesis or complement activation. It is desirable to coat the fluid contacting surfaces of the pump with a coating that satisfies these concerns. It is also desirable to coat tissue contacting surfaces on implantable pumps with such a coating.

In the preferred embodiment, an amorphous coating of a transition metal nitride or other wear-resistant biocompatible ceramic material is applied according to a method disclosed in United States Patent application Serial Number 09/071,371, filed April 30, 1998. By this method, a biocompatible, reliable, and durable room-temperature-processed amorphous coating can be provided on all blood-contacting and/or tissue contacting surfaces of the pump. A variety of biocompatible ceramic coatings may be applied by this method, including titanium nitride, silicon nitride, titanium carbide, tungsten carbide, silicon carbide, and aluminum oxide.

Titanium nitride is presently the preferred coating material. As a transition metal nitride, it is a well-known biomaterial. It is inert, fatigue resistant, biocompatible, corrosion resistant, and lightweight. In crystalline form it is presently used in tools and parts for high-temperature (up to 600°C) applications as a corrosion and oxidation-resistant coating. Titanium nitride coatings have also been used as a wear resistance coating for orthopedic implants, on dental implants and instruments, and on defibrillator electrodes, where it is applied by chemical vapor deposition. However, all of these applications use titanium nitride in its crystalline form. Unfortunately, crystalline TiN cannot be applied to plastics, magnetic materials, and other heat-sensitive and flexible materials because of its high (~800° C) coating temperature and because it chips when its substrate flexes.

blood contacting surfaces and tissue contacting surfaces of blood pumps.

Those skilled in the art will appreciate that numerous modifications can be made without departing from the scope and spirit of the present invention. The appended claims are intended to cover such modifications.

7. A blood pump as defined in claim 6, wherein the ceramic coating is formed of a transition metal nitride.

8. A blood pump as defined in claim 6, wherein the coating is formed of a material selected from the group consisting of titanium nitride, silicon nitride, titanium carbide, tungsten carbide, silicon carbide, and aluminum oxide.

9. A blood pump as defined in claim 6, wherein the ceramic coating is amorphous and conductive.

10. A blood pump as defined in claim 1 which is configured for implantation in a human patient.

11. A blood pump as defined in claim 10, wherein all tissue contacting surfaces are coated with a wear-resistant biocompatible ceramic coating.

12. A blood pump which includes stator and rotor members, wherein the stator defines a common magnetic path for flux generated by both permanent and electromagnet sources, said stator including a first radial component and first axial component attached to the first radial component which collectively define at least a portion of the common magnetic path.

13. A blood pump as defined in claim 12, further comprising a second axial component coupled at a lower end of the first radial component, the combination defining at least a portion of the common magnetic path.

position of the rotor, said controller system being configured to change the current for generation of the magnetic flux based on said signals so as to reposition the impeller within the housing.

19. The invention of claim 18 wherein the controller system determines the necessary current change parameters by means of a proportional-integral-derivative algorithm.

20. A motor for a blood pump having a pump housing and an impeller magnetically suspended within said housing, said motor comprising: a stator disposed on the inside of the housing and comprising a plurality of non-magnetic core coils radially disposed about the center of the pump, and a rotor comprising an even-numbered plurality of permanent magnets of alternating polarity affixed to the side of the impeller adjacent to the stator, forming a flux gap between the rotor and the stator, whereby the rotor may be caused to rotate when an alternating current flows through the coils.

21. The motor as described in claim 20, wherein said stator defines a radially curved surface complementary to said rotor, such that said flux gap defines a curved space between the stator and the rotor.

22. The motor as described in claim 21 wherein the flux gap is between about 0.001 inches and 0.100 inches.

23. The motor as described in claim 20, wherein said rotor further comprises a layer of magnetic material affixed to said permanent magnets on the side opposite the stator.

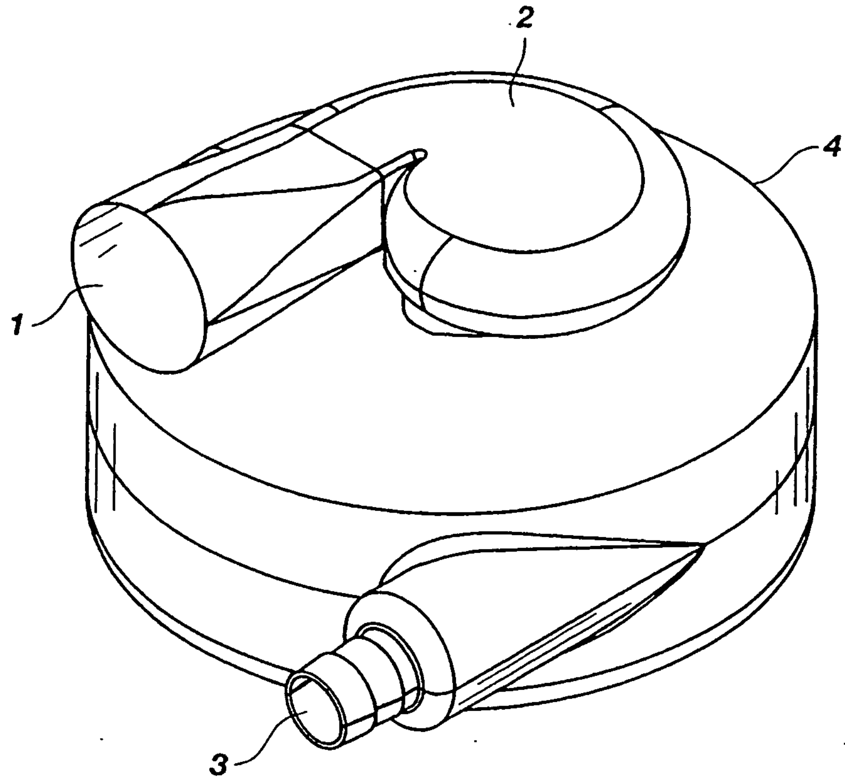


Fig. 1

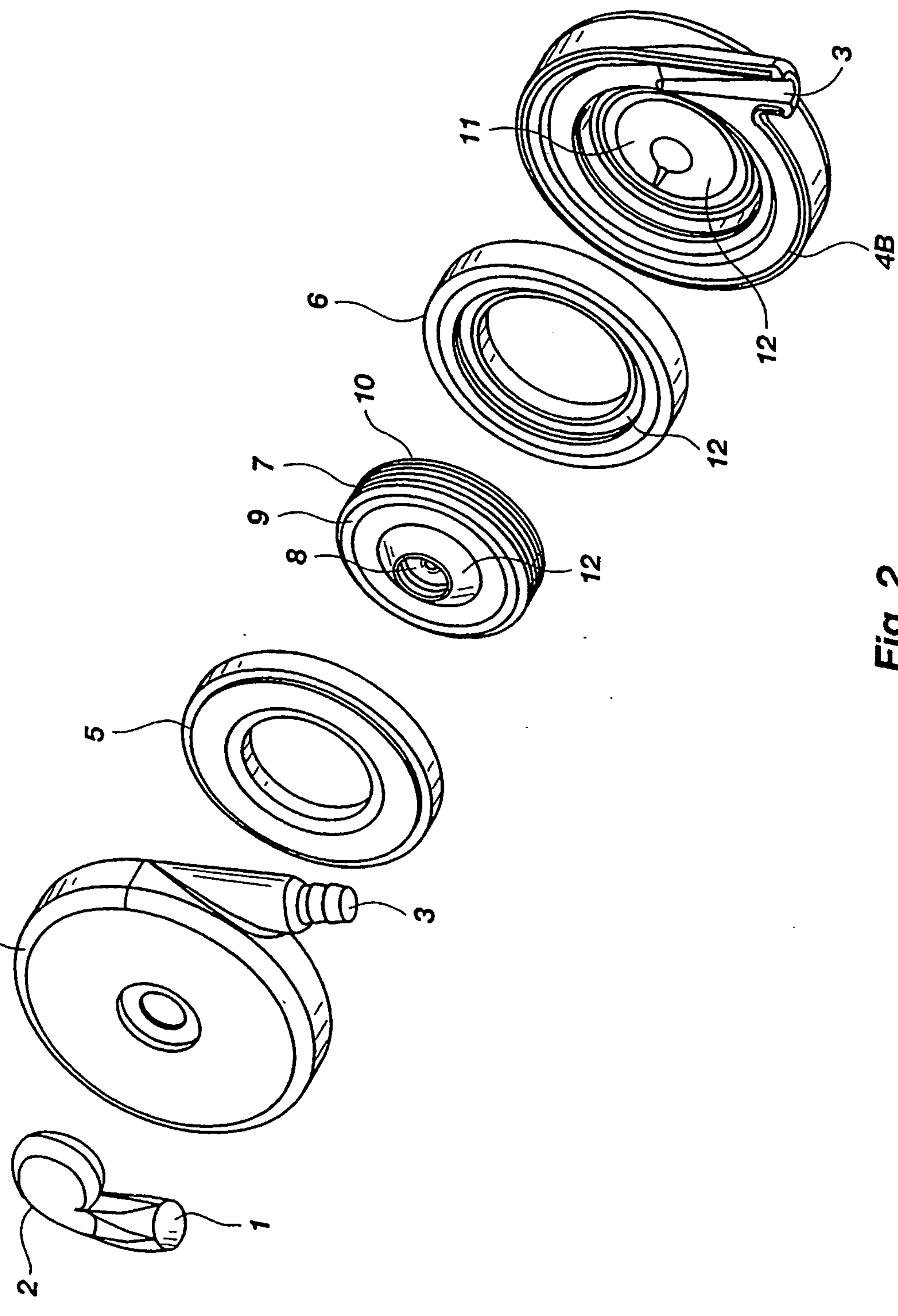


Fig. 2

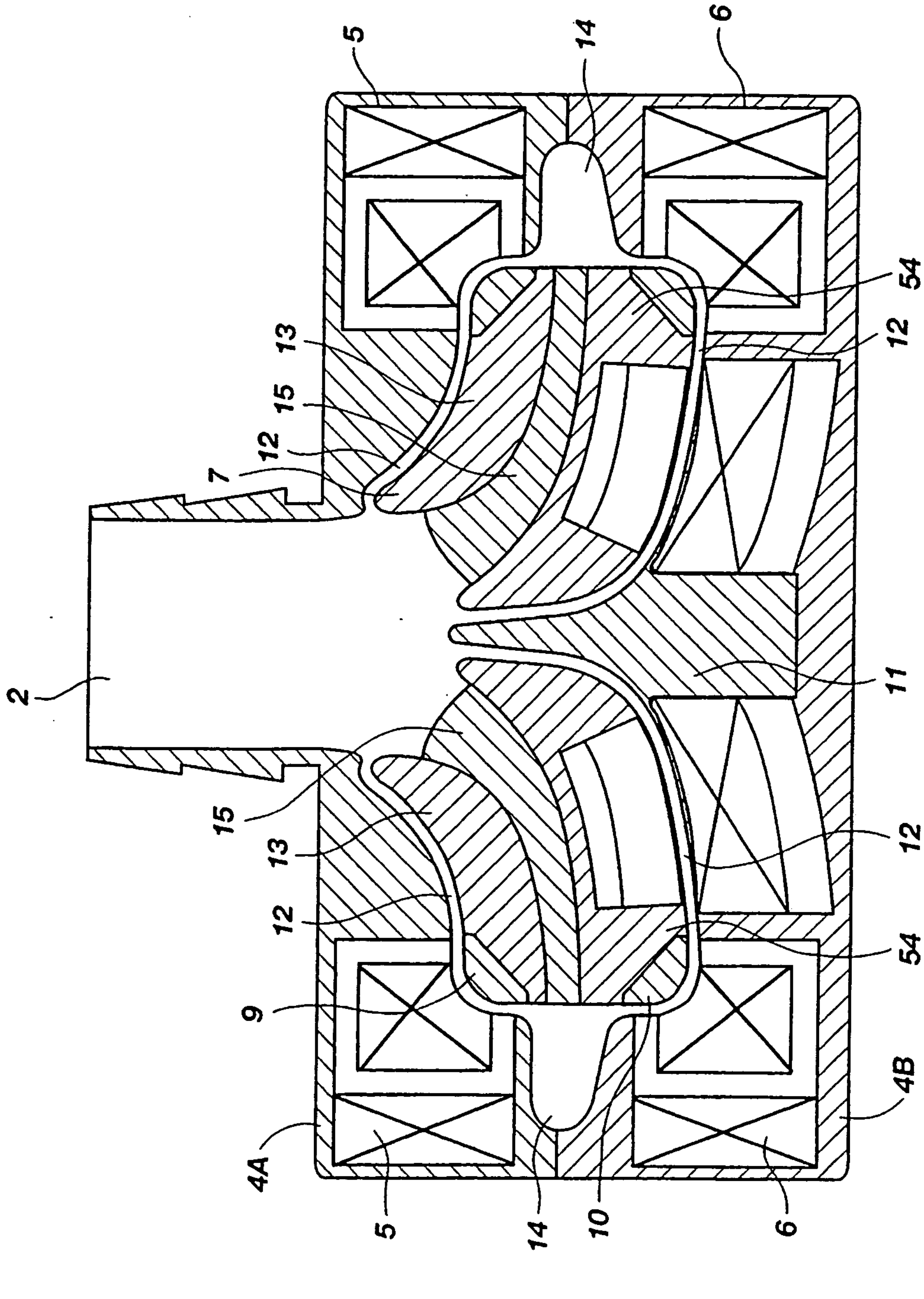


Fig. 3

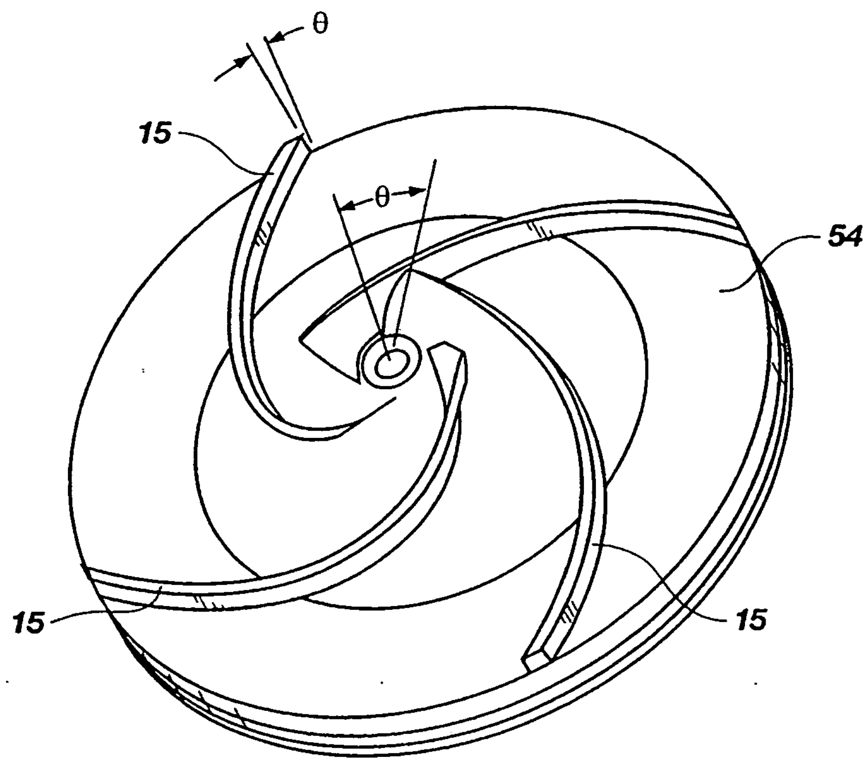


Fig. 4

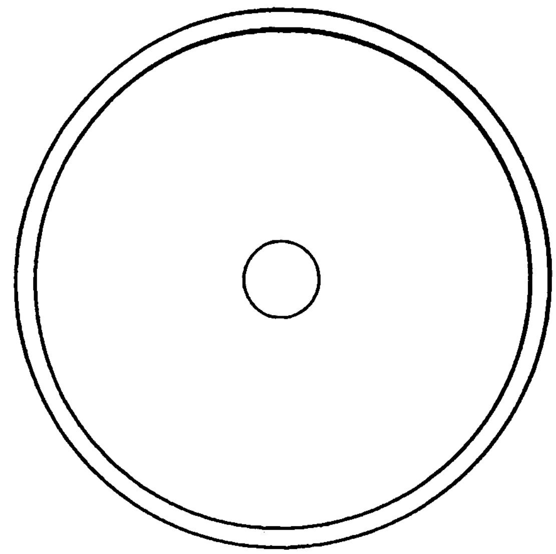


Fig. 5C

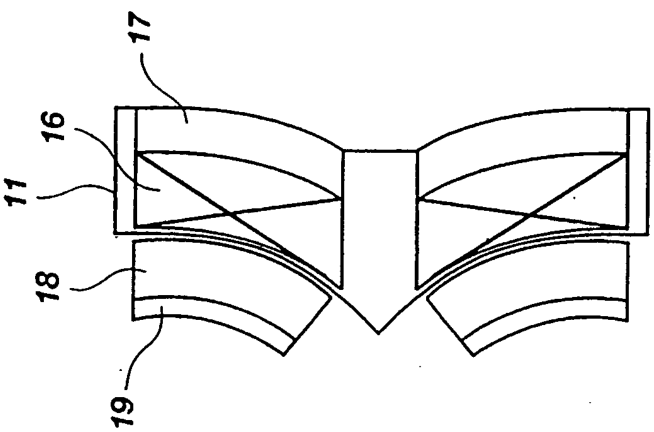


Fig. 5B

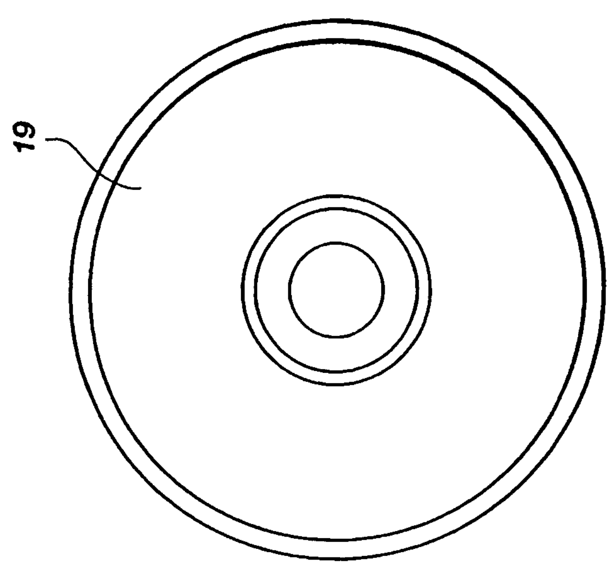


Fig. 5A

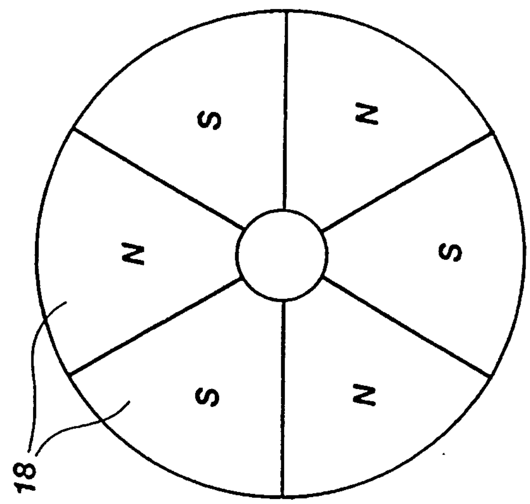


Fig. 6C

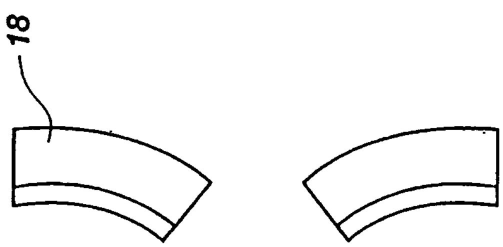


Fig. 6B

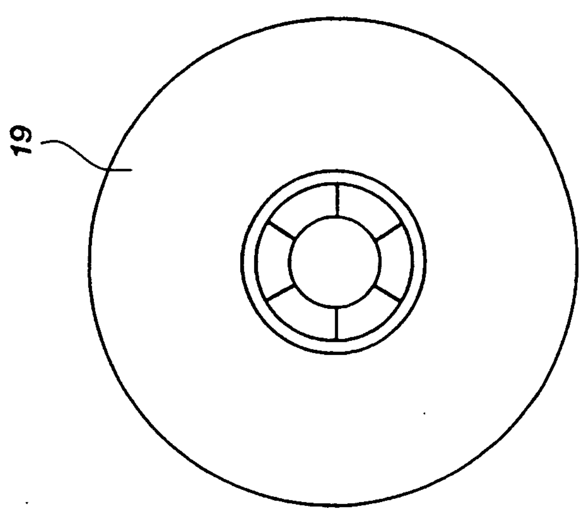


Fig. 6A

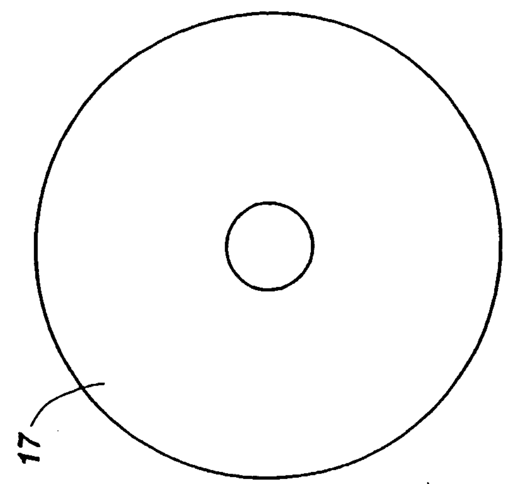


Fig. 7C

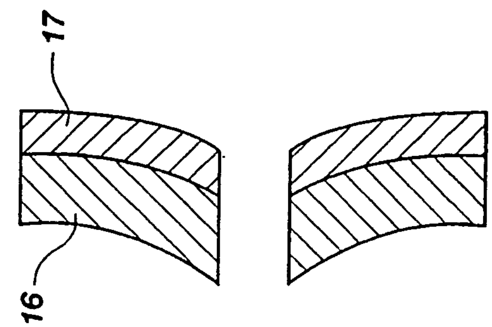


Fig. 7B

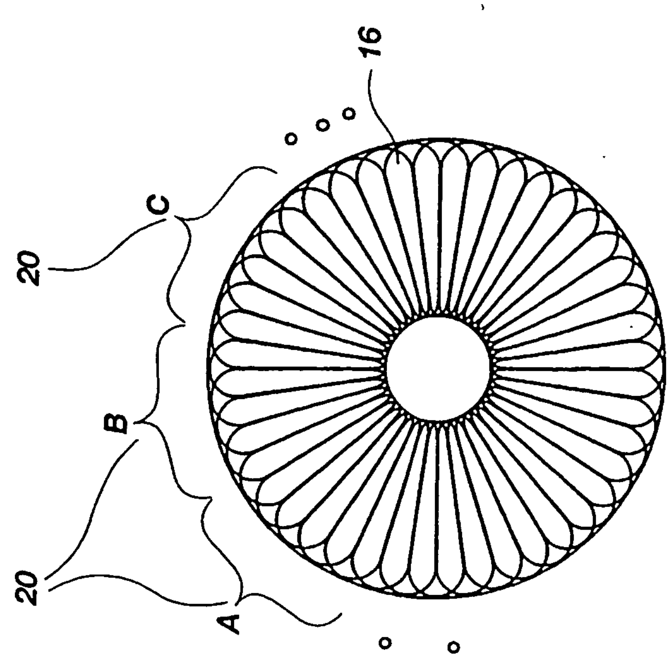


Fig. 7A

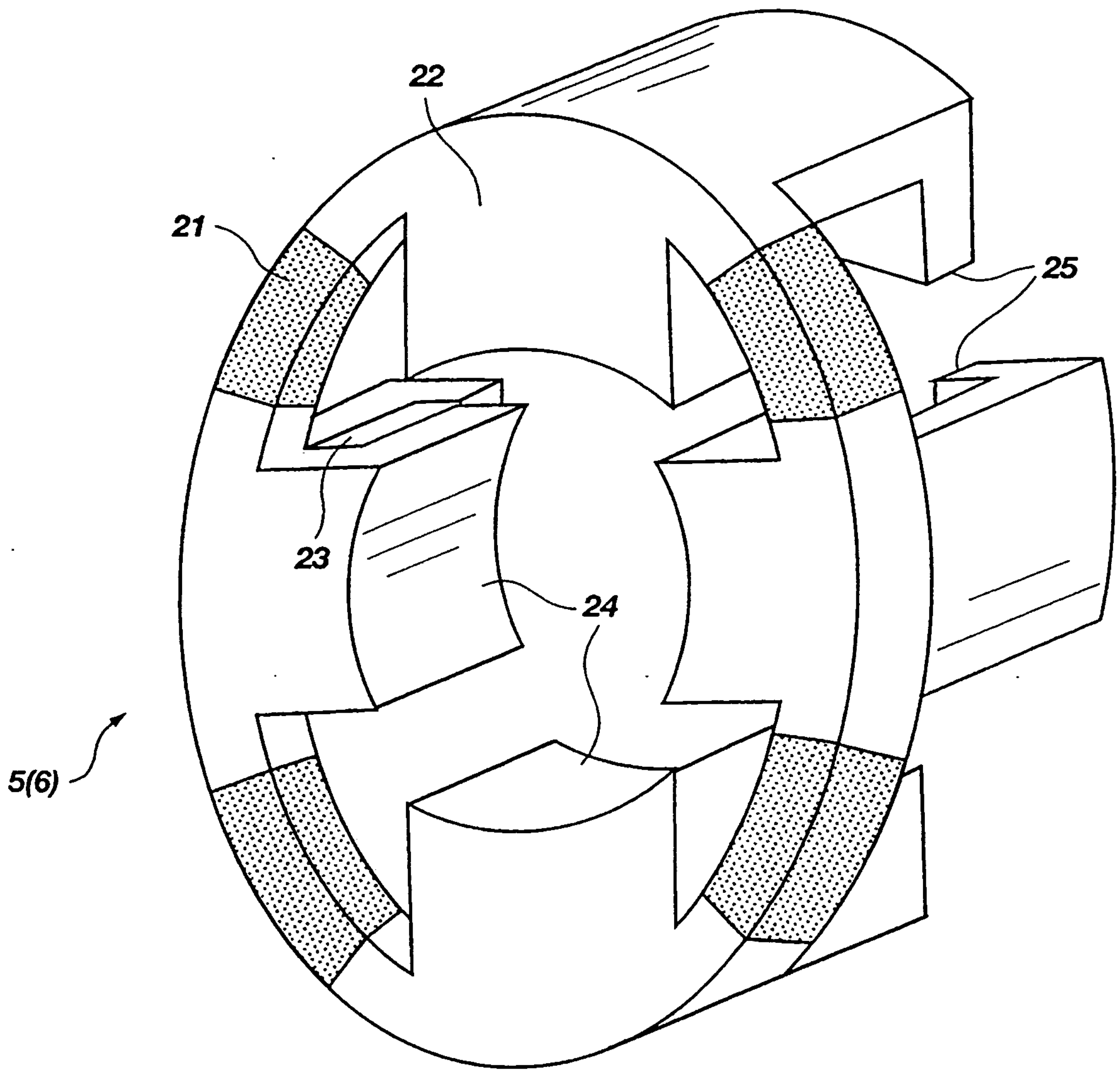


Fig. 8

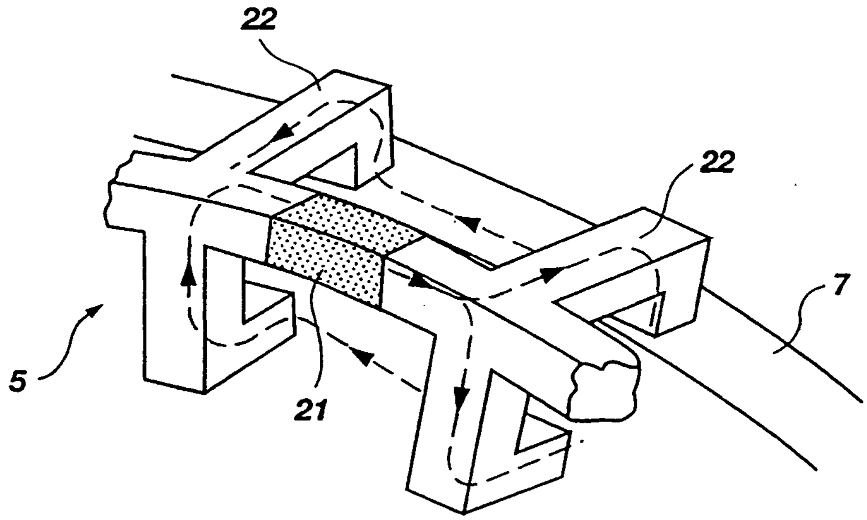


Fig. 9

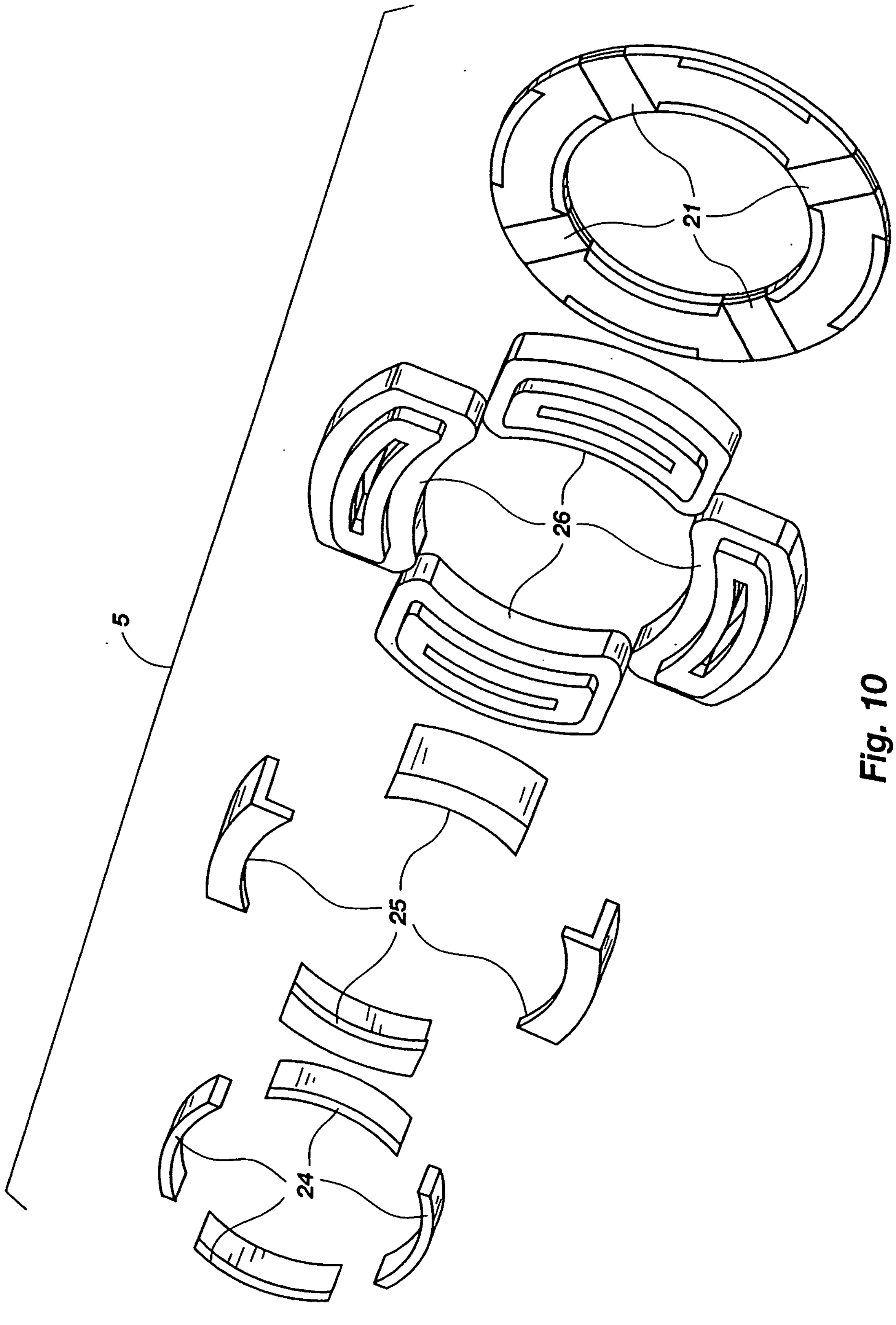


Fig. 10

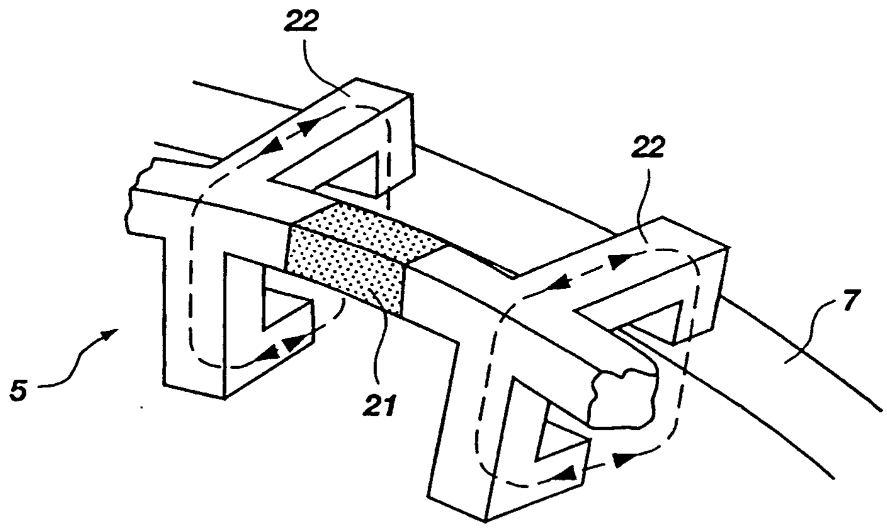


Fig. 11

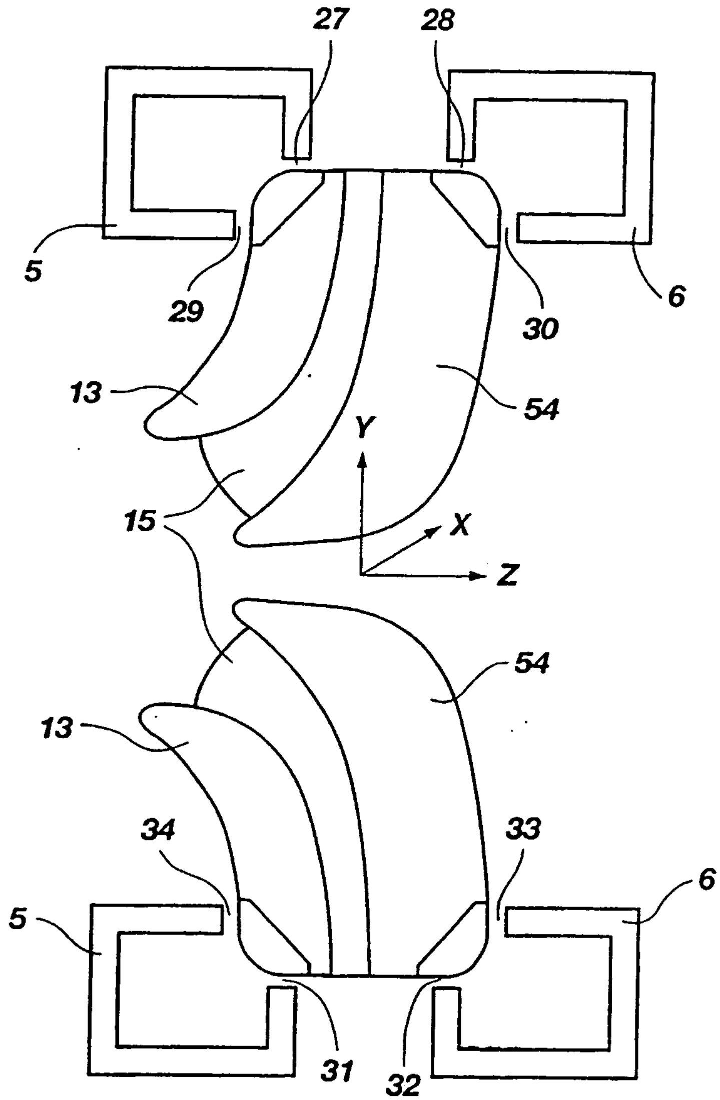


Fig. 12

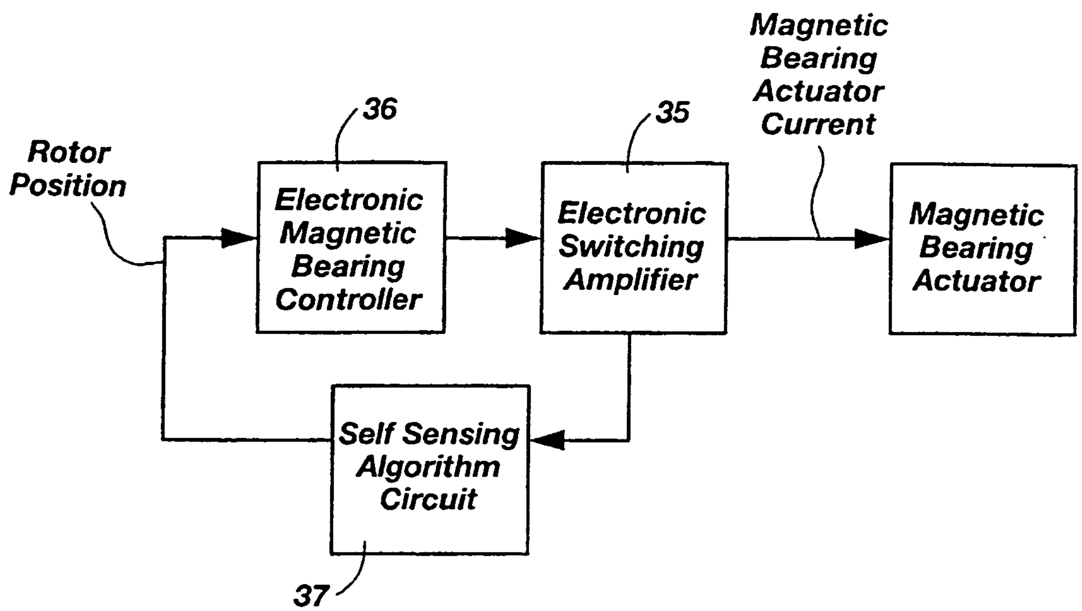

Rotor Position
36
Electronic Magnetic Bearing Controller
35
Electronic Switching Amplifier
Magnetic Bearing Actuator Current
Magnetic Bearing Actuator
Self Sensing Algorithm Circuit
37

Fig. 13

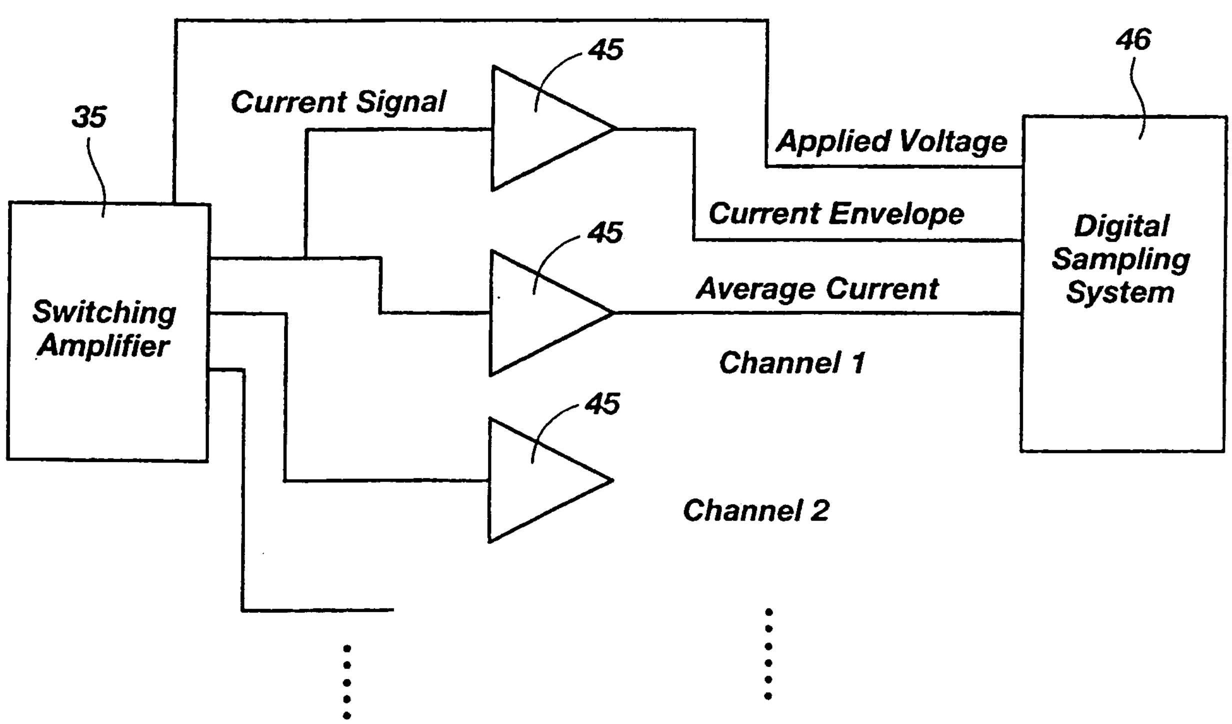

35
Switching Amplifier
Current Signal
45
45
45
Applied Voltage
Current Envelope
Average Current
Channel 1
Channel 2
46
Digital Sampling System

Fig. 15

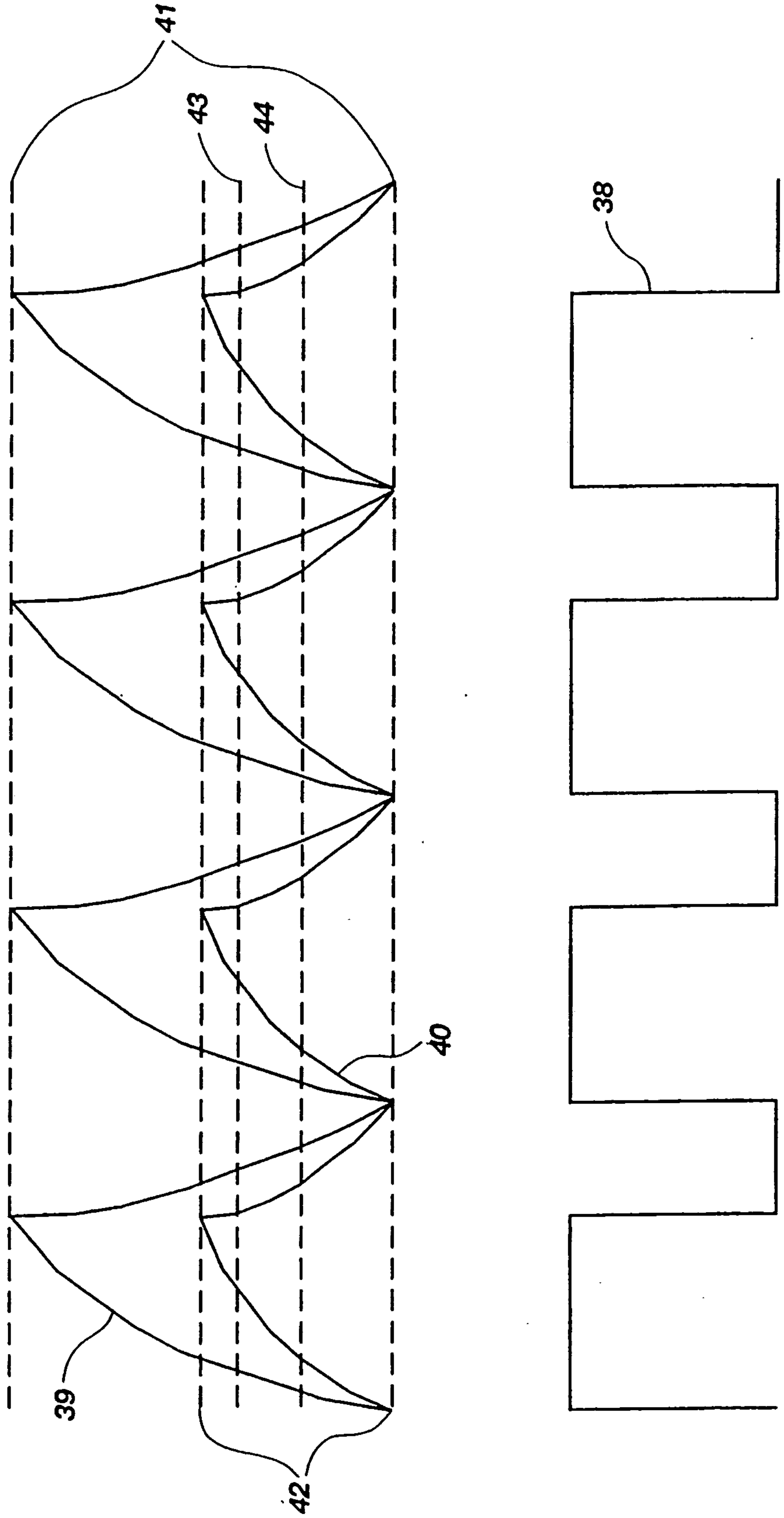


Fig. 14

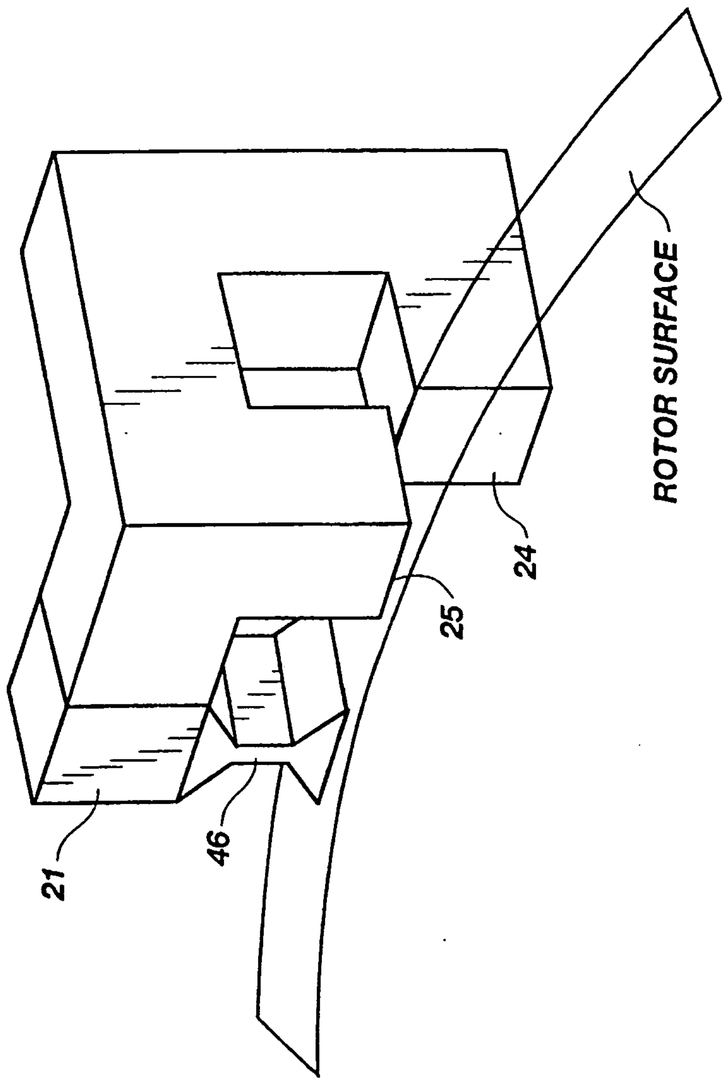


Fig. 16